

# UNITED STATE DEPARTMENT OF COMMERCE United States Patent and Trademark Office

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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO.

EXAMINER

ART UNIT PAPER NUMBER

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

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# Applicant(s) Application No. 09/529.205 KATO ET AL. Office Action Summary Art Unit Examiner Bridget E. Bunner 1647 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1 136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U S C § 133) Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment See 37 CFR 1 704(b) Status Responsive to communication(s) filed on <u>22 June 2001</u>. 1)[•] 2b) This action is non-final. 2a)∏ This action is **FINAL**. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is 3)[7] closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. **Disposition of Claims** 4) Claim(s) 7-26 is/are pending in the application. 4a) Of the above claim(s) 23 and 26 is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 7-22,24 and 25 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) 7-26 are subject to restriction and/or election requirement. **Application Papers** 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. 12) The oath or declaration is objected to by the Examiner Priority under 35 U.S.C. §§ 119 and 120 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f) a) All b) Some \* c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_\_ 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). . Off - antick for a lat of the nortified copies not received ம் 👸 The translation of the foreign language provisional application has been received 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 12 i Attachment(s) Inten, ew Şijmmary (PTO-413) Paper No.s N tope of References ( to 1 PT-1994) Notice of Chaffspark of k Parent Chapter School (1986) in 1994 Information (Exclusive Statement's Fig. 144 - - 44 - 14 Typen y 1 to you go the co

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#### **DETAILED ACTION**

### Status of Application, Amendments and/or Claims

The amendments of 13 February 2001 (Paper No. 6) and 22 June 2001 (Paper No. 12) have been entered in full. Claims 1 and 3-4 were amended. Claims 1-6 are cancelled and claims 7-26 are added.

The Applicant's response to the Notice to Comply with Sequence Listing Requirements under 37 CFR §1.821 (Paper No. 6, 13 February 2001) has been considered and is found persuasive. Therefore, the requirements set forth in the Notice to Comply (Paper No. 5, 10 January 2001) are withdrawn.

Applicant's election without traverse of Group 1 (amino acid sequence SEQ ID NO: 1) and Group 11 (nucleic acid sequence SEQ ID NO: 11) in Paper No. 12 (22 June 2001) is acknowledged.

Claims 23 and 26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12 (22 June 2001).

Claims 7-22 and 24-25 are under consideration in the instant application.

#### **Drawings**

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

#### Specification

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1a. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

1b. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: "A HUMAN PROTEIN WITH TRANSMEMBRANE DOMAINS AND DNA ENCODING THE PROTEIN".

- 1c. The first sentence of the paragraph on page 17, lines 26-27 should be reworded without adding new matter. The first sentence is missing a word after the phrase "may be possible to".
- 1d. The paragraph on page 38, line 27 and page 39, lines 1-3 should be reworded without adding new matter. It cannot be determined what cells mRNA was extracted from. It is also not clear what of the meaning of the phrase "tissues of stomach cancer delivered by the operation".

Appropriate correction is required.

# Claim Rejections - 35 USC § 101 and §112, first paragraph

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 7-22 and 24-25 are rejected under 35 U.S.C. 101 because the claimed invention is

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utility. Novel biological molecules lack well established utility and must undergo extensive experimentation.

Specifically, claims 7-22 and 24-25 are directed to an isolated nucleic acid molecule comprising the nucleic acid sequence of SEQ ID NO: 11 that encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 1 and an isolated nucleic acid molecule comprising a fragment of at least 10 nucleotides of SEQ ID NO: 11. The claims also recite an isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 1, an isolated polypeptide comprising a fragment of at least 5 contiguous amino acids of SEQ ID NO: 1, and an isolated polypeptide consisting of a naturally occurring allelic variant of the polypeptide comprising the amino acid sequence of SEQ ID NO: 1. The claims are further directed to an expression system comprising the polynucleotide that produces the polypeptide, a recombinant host cell, a process of producing a recombinant host cell and polypeptide, and a method for preventing, treating, or ameliorating a medical condition by a administering a composition comprising the polypeptide.

The specification asserts that the human polynucleotide (SEQ ID NO: 11) and polypeptide (SEQ ID NO: 1) of the present invention are involved in numerous cellular activities. Such activities include cell proliferation, cell differentiation, cytokine production, immune stimulation or suppression, B lymphocyte antigen activity, regulation of hematopoiesis, tissue growth/regeneration, wound healing, tissue repair, activin/inhibin related activities, chemotactic/chemokinetic activity, and hemostatic or thrombolytic activity (pg 14-34). However, the instant specification does not teach any significance or functional characteristics of

also does not disclose any methods of working examples that indicate the polyhocicologic and

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polypeptide of the instant invention are involved in any of the abovementioned activities. Since significant further research would be required of the skilled artisan to determine how the claimed polypeptide is involved with the above-mentioned activities, the asserted utilities are not substantial. The specification asserts the following as patentable utilities for the claimed putative polynucleotide and polypeptide (SEQ ID NO: 11 and SEQ ID NO: 1, respectively):

- 1) to produce antibodies (pg 1, lines 10-11)
- 2) as probes for gene diagnosis (pg 1, lines 12-13; pg 12, lines 4-5, 7-8)
- 3) for gene therapy (pg 1, line 13)
- 4) in assays to detect corresponding ligands (pg 1, lines 17-18; pg 13, lines 3-4)
- 5) to screen novel pharmaceutical agents (pg 1, lines 18-19).
- 6) as tissue markers (pg 11, lines 24-27; pg 12, line 27)
- 7) to identify chromosomes or gene positions (pg 12, lines 1-3)
- 8) for PCR primers (pg 12, lines 5-6)
- 9) to identify other binding proteins and DNA encoding these proteins (pg 12, lines 18-20; pg 13, lines 6-10)
- 10) to treat various human diseases or disorders (pg 17-38)

Each of these shall be addressed in turn.

1) to produce antibodies. This asserted utility is credible and substantial but not specific. Antibodies can be made to any polypeptide. However, the specification discloses nothing specific and substantial about the polypeptides, therefore both polypeptides and their antibodies

specific. Hybridization probes can be designed from any polynucleotide sequence. Further, the

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specification does not disclose specific cDNA, DNA, or RNA targets. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

- 3) for gene therapy. This asserted utility is credible but not specific or substantial. Such can be performed for any polynucleotide. Further, the specification does not disclose specific diseases associated with a mutated, deleted, or translocated gene of the instant application (SEQ ID NO: 11). Significant further experimentation would be required of the skilled artisan to identify individuals with such a disease and to determine the route of administration of the gene, as well as quantity and duration of treatment. Since this asserted utility is also not presented in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.
- 4) in assays to detect corresponding ligands. This asserted utility is credible but not substantial or specific. Such assays can be performed with any polypeptide. Additionally, the specification discloses nothing specific or substantial about the ligands that are identified by this method. Since this asserted utility is also not presented in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.
- 5) to screen pharmaceutical agents. This asserted utility is credible but not specific or substantial. Such assays can be performed with any polypeptide. Additionally, the specification discloses nothing specific or substantial for the pharmaceutical agents that can be identified by this method. Since this asserted utility is also not presented in mature form, so that it could be

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6) as tissue markers. This asserted utility is credible but not substantial or specific. Such marker assays can be performed with any polynucleotide or polypeptide. Further, the specification does not disclose specific DNA or amino acid sequences for use as markers for RFLP, to prepare primers, or to amplify DNA. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

- 7) to identify chromosomes or gene positions. This asserted utility is credible but not substantial or specific. Such assays can be performed with any polynucleotide. Further, the specification does not disclose a specific DNA target. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.
- 8) for PCR primers. This asserted utility is credible but not substantial or specific. Primers can be designed from any polynucleotide sequence. Further, the specification does not disclose a specific DNA target. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.
- 9) to identify other binding proteins and DNA encoding these proteins. This asserted utility is credible but not specific or substantial. Such assays can be performed with any polynucleotide and polypeptide. Additionally, the specification discloses nothing specific or substantial for the binding proteins or nucleic acid molecules that can be identified by this method. Since this asserted utility is also not present in mature form, so that it could be readily

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specific or substantial. The specification does not disclose disorders associated with a mutated, deleted, or translocated gene of the instant application (SEQ ID NO: 11). The specification does not disclose which disorders are associated with altered levels or forms of the polypeptide (SEQ ID NO: 1). Significant further experimentation would be required of the skilled artisan to identify individuals with such a disease or disorder and to determine the quantity and duration of treatment. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

3. Claims 7-22 and 24-25 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 7-22 and 24-25 recite an isolated nucleic acid molecule comprising the nucleic acid sequence of SEQ ID NO: 11 that encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 1 and an isolated nucleic acid molecule comprising a fragment of at least 10 nucleotides of SEQ ID NO: 11. The claims also recite an isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 1, an isolated polypeptide comprising a fragment of at least 5 contiguous amino acids of SEQ ID NO: 1, and an isolated polypeptide consisting of a naturally occurring allelic variant of the polypeptide comprising the amino acid

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producing a recombinant host cell and polypeptide, and a method for preventing, treating, or ameliorating a medical condition by a administering a composition comprising the polypeptide.

The specification teaches that the invention of the instant application "encompasses allelic variants of the disclosed polynucleotides or proteins; that is, naturally-occurring alternative forms of the isolated polynucleotide which also encode proteins which are identical, homologous, or related to that encoded by the polynucleotides" (pg 65, lines 26-27; pg 66, lines 1-3). ). However, the specification does not disclose methods or examples to enable one skilled in the art to obtain a "naturally occurring" polypeptide of SEQ ID NO: 1 or any allelic variants of SEQ ID NO: 1, particularly from other species besides human. The specification does not disclose the chromosomal locus for the human polynucleotide/polypeptide of the instant application. Since allelic variants must be at the same locus as the gene (SEQ ID NO: 11), it would be undue experimentation for one skilled in the art to identify the locus and map variants to determine which are alleles. The specification discloses that the polynucleotide (SEQ ID NO: 11) and the polypeptide (SEQ ID NO: 1) of the instant application can be used to treat numerous human diseases and disorders. However, the specification does not disclose any methods or working examples to demonstrate that the polynucleotide and polypeptide prevent, treat, or amerliorate any medical condition in any mammalian subject. Undue experimentation would be required of the skilled artisan to determine the disease affected by altered levels or mutated forms of the polynucleotide and polypeptide (SEO ID NO: 11 and SEO ID NO: 1, respectively). Furthermore, a large quantity of experimentation would be required to determine the quantity

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The specification only teaches an isolated human polynucleotide comprising SEQ ID NO: 11 and an isolated polypeptide comprising SEQ ID NO: 1. The specification also discloses that "any cDNA that is subjected to insertion or deletion of one or plural nucleotides and/or substitution with other nucleotides in SEQ ID NOs: 11-20... shall come within the scope of the present invention" (pg 10, lines 25-29). The specification continues to teach that "any protein that is formed by these modifications comprising insertion or deletion of one or plural amino acids and/or substitution with other amino acids shall come within the scope of the present invention, as far as the protein possesses the activity of any protein having the amino acid sequences represented by SEQ ID NOs: 1-10" (pg 10, lines 30-32; pg 11, lines 1-3). However, the specification does not teach a nucleic acid molecule comprising a fragment of at least 10 nucleotides of SEQ ID NO: 11 or a nucleic acid molecule which encodes a polypeptide fragment comprising at least 5 contiguous amino acid residues of SEO ID NO:1. Further, the specification does not teach an isolated polypeptide fragment comprising at least 5 contiguous amino acids of SEO ID NO: 1. Additionally, the specification does not disclose functional or structural characteristics of the polynucleotides and polypeptides and any variants in the context of a cell or organism.

The problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. While it is known that many amino acid substitutions are generally possible in any given protein the positions within the protein's sequence where such amino acid substitutions can

are critical to the protein's structure function relationship, e.g. such as various sites or regions

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directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These or other regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions (see Wells, 1990, Biochemistry 29:8509-8517; Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495). However, Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions. Although the specification outlines art-recognized procedures for producing and screening for active muteins, this is not adequate guidance as to the nature of active derivatives that may be constructed, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. Even if an active or binding site were identified in the specification, they may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity. The art recognizes that function cannot be predicted from structure alone (Bork, 2000, Genome Research 10:398-400; Skolnick et al., 2000, Trends in Biotech. 18(1):34-39. especially p. 36 at Box 2; Doerks et al., 1998, Trends in Genetics 14:248-250; Smith et al., 1997, Nature Biotechnology 15:1222-1223; Brenner, 1999, Trends in Genetics 15:132-133; Bork et al.,

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Due to the large quantity of experimentation necessary to determine an activity or property of the disclosed polypeptide (SEQ ID NO: 1) such that it can be determined how to use the claimed polynucleotide (SEQ ID NO: 11) and to generate the derivatives recited in the claims and screen same for activity, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art establishing that biological activity cannot be predicted based on structural similarity and the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite particular structural and functional limitations and also embrace a broad class of structural fragments and variants, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

4. Claims 8, 10-20, and 24-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 8, 10-20, and 24-25 are directed to an isolated nucleic acid molecule comprising a fragment of at least 10 nucleotides of SEQ ID NO: 11. The claims also recite an isolated polypeptide comprising a fragment of at least 5 contiguous amino acids of SEQ ID NO: 1, and an isolated polypeptide consisting of a naturally occurring allelic variant of the polypeptide

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The specification teaches human a polynucleotide (SEQ ID NO: 11) and polypeptide (SEQ ID NO: 1). The specification also discloses that "any cDNA that is subjected to insertion or deletion of one or plural nucleotides and/or substitution with other nucleotides in SEQ ID NOs: 11-20, 23, 25, 27, 29, 31, 35, 37, and 39 shall come within the scope of the present invention" (pg 10, lines 25-29). Furthermore, the specification continues to teach that "any protein that is formed by these modifications comprising insertion or deletion of one or plural amino acids and/or substitution with other amino acids shall come within the scope of the present invention, as far as the protein possesses the activity of any protein having the amino acid sequences represented by SEQ ID NOs: 1-10" (pg 10, lines 30-32; pg 11, lines 1-3). However, the specification does not teach functional or structural characteristics of the polynucleotides and polypeptides in the context of a cell or organism. The description of one polynucleotide species (SEQ ID NO: 11) and one polypeptide species (SEQ ID NO: 1) is not adequate written description of an entire genus of functionally equivalent polynucleotides and polypeptides which incorporate all variants and fragments.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See Vas-Cath at page 1116).

the detailed chemical structure of the encompassed polyhucleotide and polypeptide, and

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therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an isolated nucleic acid molecule consisting of the nucleotide sequence of SEQ ID NO: 11 and an isolated polypeptide consisting of the amino sequence of SEQ ID NO: 1, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

## 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 12, 20-22, and 24-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which unplicant records as the invention

relative, and the art does not recognize a single set of conditions as stringent. The specification

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also does not provide an unambiguous definition for the term. In the absence of a recitation of clear hybridization conditions (e.g., "hybridizes at wash conditions of  $\mathbf{A}$  X SSC and  $\mathbf{B}$  % SDS at  $\mathbf{C}^{o}\mathbf{C}^{o}$ "), the claims fail to define the metes and bounds of the varying structures of polynucleotides recited in the claimed methods.

7. Claims 20-22 and 24-25 are rejected as being indefinite because a claim that depends from a claim which "consists of" the recited elements or steps cannot add an element or step. See MPEP § 2111.03.

# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 8. Claims 8 and 12-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Marra et al (Accession Number W42223, direct submission, EST database, 11 September 1996). Marra et al. teaches an isolated nucleic acid molecule comprising a fragment of at least 10 nucleotides of SEQ ID NO: 11 of the instant application (See sequence alignment attached to this Office Action as Appendix A; see nucleotides 242-266 of Marra et al.; see also nucleotides 236-260 of SEQ ID NO: 11 of the instant application).
- 9. Claims 20-22 and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Friedman et al. (Accession Number AAA41546, SPTREMBL database, 27 April 1993).

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amino acids of SEQ ID NO: 1 of the instant application (See amino acids 102-107 of Friedman et al.; see also amino acids 89-94 of SEQ ID NO: 1 of the instant application).

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#### Conclusion

No claims are allowable.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Au-Young, J. U.S. patent 5,856,136

Hillier et al. Accession Number H02338. 20 June 1995.

Marra et al. Accession Number AA060412. 23 September 1996.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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